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NOV 2 0 2002

K023003

510(k) Summary of Safety and Effectiveness
Prepared September 6, 2002

Submitted by: R2 Technology, Inc.
1195 W. Fremont Avenue
Sunnyvale, CA 94087

Contact Person: Kathy O'Shaughnessy
Vice President, Regulatory and Clinical Affairs

Department:

Product Name: ImageChecker-CT Workstation
Common Name: Medical Imaging Workstation

Classification: LLZ; Class II; CFR 21 892.2050

Predicate Devices: TeraRecon, Aquarius Workstation (K011142)
Siemens Realtime 3D Diagnostic Workstation (K973010)
GE Advantage Workstation 4.1 (K020483)

Device Description:

The ImageChecker-CT System is a combination of dedicated computer software and hardware. The System uses an off-the-shelf personal computer with Windows and Linux-based CPUs, a hard drive, and a single monitor.

Summary of Intended Use:

The ImageChecker-CT is indicated for use as a general imaging workstation, and is intended to be used to acquire, store, transmit and display images from medical scanning devices.

Specific indications for use for the ImageChecker-CT Workstation are the display of a composite view of 2D cross-sections, and 3D volumes of chest CT images, including findings or regions of interest ("ROI") identified by the radiologist **or** Computer Assisted Detection ("CAD") findings.

Comparison with Predicate Device:

The ImageChecker-CT Workstation and the predicate devices support network connectivity, and use tools such as 2D image review and 3D volume segmentation views. All devices support DICOM protocol for communication of images with other medical imaging devices.

Studies:

The ImageChecker-CT Workstation will undergo design verification tests for conformance with specifications.

Conclusion:

The ImageChecker-CT Workstation has the same intended use as the predicate devices and very similar indications and technological characteristics. The minor differences in the device's technological characteristics do not cause any new questions of safety and effectiveness. Thus, the ImageChecker-CT Workstation is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2002

Kathy O'Shaughnessy, Ph.D.
Vice President, Regulatory
and Clinical Affairs
R2 Technology, Inc.
1195 W. Fremont Avenue
SUNNYVALE CA 94087-3832

Re: K023003
Trade/Device Name: ImageChecker-CT Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 6, 2002
Received: September 9, 2002

Dear Dr. O'Shaughnessy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K023003

INDICATION FOR USE:

The general indications for use of the ImageChecker-CT Workstation are as a general imaging workstation to assist radiologists in reviewing digital computed Tomography (CT) images of the chest.

Specific indications for use for the ImageChecker-CT Workstation are the display of a composite view of 2D cross-sections, and 3D volumes of chest CT images, including findings or regions of interest ("ROI") identified by the radiologist **or** Computer Assisted Detection ("CAD") findings.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: x_____ -OR- Over-The-Counter: _____
(Per 21 CFR 801.109)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
Radiological Devices
510(k) K023003